

Dkt. #1014-PCT-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : BIANCHI, et al.

U.S. Serial No.: Not Yet Known, corresponding to
International Application No.
PCT/IT2003/000265, filed April 29, 2003,
which claims priority of U.S. Serial No.
60/393,994, filed July 3, 2002

Filed Date : Herewith

For : USE OF HMGB1 IN THE TREATMENT OF TISSUE
DAMAGE AND/OR TO PROMOTE TISSUE REPAIR

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December 22, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop Patent Application

Sir/Madam:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants would like to direct the Examiner's attention to the following references which are listed below and on Forms PTO/SB/08A and PTO/SB/08B (which are attached hereto as **Exhibit A**), and each individual reference further attached as **Exhibits 1** through **15**.

1. PCT International Search Report for BIANCHI, et al., Int'l Application No. PCT/IT2003/000265, Filed April 29, 2003, Dated November 13, 2003. [**Exhibit 1**]
2. International Publication Number WO 00/47104 A2 for PICOWER INST MED RES, Published August 17, 2000. "Antagonists of HMGB1 for treating Inflammatory Conditions". [**Exhibit 2**]

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3. International Publication Number WO 01/89526 A1 for NORTH SHORE LONG ISLAND JEWISH REASEARCH INSTITUTE, Published November 29, 2001. "Inhibition of Inflammatory Cytokine Production by Cholinergic Agonists and Vagus Nerve Stimulation". **[Exhibit 3]**
4. FANG, et al; "The Significance of Changes in High Mobility Group-1 Protein mRNA Expression in Rats after Thermal Injury", Shock (Augusta, G.A.) United States APR, 2002; Vol. 17, No. 4, April 2002, Pgs. 329-333, XP009020804. **[Exhibit 4]**
5. FAGES, et al; "Regulation of Cell Migration by Amphoterin", Journal of Cell Science, Essex, GB; Vol. 113, No. 4, February 2000, Pages 611-620, XP001070170. **[Exhibit 5]**
6. MULLER, et al.; "The Double Life of HMGB1 Chromatin Protein: Architectural Factor and Extracellular Signal", EMBO (EUROPEAN MOLECULAR BIOLOGY ORGANIZATION) Journal; Vol. 20, No. 16, August 15, 2001, Pages 4337-4340, XP002261324. **[Exhibit 6]**
7. WANG, et al.; "HMGB1 as a late Mediator of Lethal Systemic Inflammation", American Journal of Respiratory and Critical care Medicine; Vol.164, No. 10, Part 1, November 15, 2001, Pages 1768-1773. **[Exhibit 7]**
8. WANG, et al.; "HMG-1 as a Late Mediator of Endotoxin Lethality in Mice", American Association for the Advancement of Science, U.S.; Vol. 285, July 9, 1999, Pages 248-251, XP002940163. **[Exhibit 8]**

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9. International Publication Number WO 02/092004 A3 for NORTH SHORE-LONG ISLAND JEWISH RESEARCH INSTITUTE, et al., Published November 21, 2002. "USE OF HMG FRAGMENTS AS ANTI-INFLAMMATORY AGENTS". **[Exhibit 9]**
10. International Publication Number WO 02/074301 A1 for Fink Mitchell P., Tracey Kevin J. (US), Ulloa Luis (US); UNIV PITTSB; Published September 26, 2002. "Method of Using Pyruvate and/or its Derivatives for the Treatment of Cytokine-Mediated Inflammatory Conditions". **[Exhibit 10]**
11. YANG HUAN, et al.; "HMGB1 as a Cytokine and Therapeutic Target", Journal of Endotoxin Research, Vol. 8, No. 6, Pages 469-472, XP009020930. **[Exhibit 11]**
12. SCAFFIDI PAOLA, et al., "Release of Chromatin Protein HMGB1 by Necrotic Cells Triggers Inflammation", NATURE (London), Vol. 418, no. 6894, July 11, 2002, Pages 191-195, XP009020930. **[Exhibit 12]**
13. International Publication Number WO 91/23611 A2 for BULLERDIEK JOERN, Published July 3, 1997. "Nucleic Acid Sequences of Genes of the High Mobility Group Proteins and Uses Thereof". **[Exhibit 13]**
14. YANG R, et al.; "Ethyl Pyruvate Modulates Inflammatory Gene Expression in Mice Subjected to Hemorrhagic Shock", American Journal of Physiology: Gastrointestinal and Liver Physiology, American Physiological Society, U.S., Vol. 283, 2002, Pages G212-G221, XP008019310. **[Exhibit 14]**
15. SIMS C A, et al.; "Ringer's Ethyl Pyruvate Solution Ameliorates Ischemia/ Reperfusion-Induced Intestinal Mucosal Injury in Rats", Critical Care Medicine, Williams

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and Wilkings Company, Baltimore, MA, U.S., Vol. 29, No. 8,
2001, Pages 1513-1518, XP008019328. **[Exhibit 15]**

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this IDS. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	2
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Complete if Known

Application Number	Not Yet Known
Filing Date	Herewith
First Named Inventor	BIANCHI, Marco
Art Unit	Not Yet Known
Examiner Name	Not Yet Known
Attorney Docket Number	1014-PCT-US

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ² -Number ⁴ -Kind Code ³ (if known)				
	2	WO 00/47104 A2	08-17-2000	PICOWER INST MED RES		
	3	WO 01/89526 A 1	11-29-2001	North Shore Long Island Jewish Research Institute		
	9	WO 02/092004 A2	11-21-2002	NORTH SHORE LONG ISLAND JEWISH RES. INSTIT.		
	10	WO 02/074301 A1	09-26-2002	Fink Mitchell P.		
	13	WO 97/23611 A 2	07-03-1997	BULLERDIEK JOER		

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.¹ Applicant's unique citation designation number (optional).² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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PTO/SB/08B (02-03)

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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	Filing Date	Herewith
	First Named Inventor	BIANCHI, Marco
	Art Unit	Not Yet Known
	Examiner Name	Not Yet Known
Sheet 2 of 2	Attorney Docket Number	1014-PCT-US

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	PCT International Search Report for BIANCHI, et al., Int'l Application No. PCT/IT2003/000265, Filed April 29, 2003, Dated November 13, 2003.	
	4	FANG, et al; "The Significance of Changes in High Mobility Group-1 Protein mRNA Expression in Rats after Thermal Injury", Shock (Augusta, G.A.) United States APR, 2002; Vol. 17, No. 4, April 2002, Pgs. 329-333, XP009020804.	
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	7	WANG, et al.; "HMGB1 as a late Mediator of Lethal Systemic Inflammation", American Journal of Respiratory and Critical care Medicine; Vol.164, No. 10, Part 1, November 15, 2001, Pages 1768-1773.	
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	15	SIMS C A, et al.; "Ringer's Ethyl Pyruvate Solution Ameliorates Ischemia/ Reperfusion-Induced Intestinal Mucosal Injury in Rats", Critical Care Medicine, Williams and Wilkins Company, Baltimore, MA, U.S., Vol. 29, No. 8, 2001, Pages 1513-1518, XP008019328	

Examiner Signature	Date Considered
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1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

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